

SPECIFICATION

A radiation coagulator

5 The invention relates to a radiation coagulator comprising an electric incandescent filament as the source of radiation and a radiation outlet system including a heat-radiation-transmitting tissue-pressing member made of a crystalline dielectric material capable of transmitting the radiation and affording a pressure surface for pressing against living body tissue.

A coagulator of this kind is known from German Offenlegungsschrift specification 27 17 421. It is very suitable for stopping relatively weak bleeding. But it is also desirable to be able to stop relatively strong bleeding and further reduce the adhesion of the tissue-pressing member to the tissue. A coagulator device should also be suitable for stopping bleeding in very soft, sensitive tissue such as liver tissue. For some purposes, e.g. for closing or obliteration of blood vessels under the surface of the skin, it is also desirable to restrict the evolution of heat in the skin adjacent the pressing surface and the immediately adjacent layer of tissue, so that coagulation begins at a certain distance from the skin surface.

An object of the invention, therefore, is to develop a radiation coagulator of the initially-mentioned kind so as to prevent excessive evolution of heat at the surface of the tissue in contact with the tissue-pressing member, and further reduce the adhesion of the tissue to the tissue-pressing surface.

According to the present invention from one aspect a radiation coagulator comprises a source of heat radiation in the form of an electric incandescent filament, and a radiation outlet including a radiation-transmitting tissue-pressing member made of a crystalline dielectric material capable of transmitting the heat radiation and affording a pressure surface for application to body tissue to be treated, and is characterised in that by virtue of the shape and dimensions of the tissue-pressing member and the thermal conductivity and thermal capacity of its material, in conjunction with an associated heat sink if required, the member in use exerts a substantial and rapid heat-removal and cooling effect on the tissue immediately adjacent to its pressure surface.

The invention from another aspect comprises a radiation coagulator which includes an electric incandescent filament as a source of heat radiation and a radiation outlet system including a radiation-transmitting tissue-pressing member made of a crystalline dielectric material capable of transmitting the heat radiation and affording a pressure surface for pressing against body tissue, and is characterised in that the radiation power density at the pressure surface is not more than 150 W/cm^2 , preferably not more than 100 W/cm^2 , and the thickness of the tissue-pressing member, measured in the direction at right angles to the pressure surface, is, on average over the pressure surface, is at least 4mm.

Advantageously the heat dissipating power of the radiation outlet system including the tissue-pressing member is such that when the coagulating radiation

is transmitted, whilst the pressure surface is adjacent typical living body tissue such as muscle tissue, the pressure surface of the tissue-pressing member is heated by not more than 50°C in 2 seconds. More particularly, the temperature increase during the treatment period should not be so great that the tissue adjacent the pressure surface dries up completely; more particularly the tissue must not be carbonized.

Since the tissue-pressing member, owing to its shape and physical characteristics as stated, has a high heat absorption and heat removal capacity relative to the power density of the radiation, the temperature increase occurring at the pressure surface during the coagulation process is considerably slower and more uniform than in the known radiation coagulators, so that the coagulation region is deeper and without a carbonized surface layer preventing the entry of radiation; thus results in a surprising improvement in stopping bleeding and reducing the adhesion of the tissue to the tissue-pressing surface. If, as is advantageously the case, the tissue-pressing member does not have any exposed sharp cutting edges, even sensitive tissue such as liver tissue can be coagulated without the risk of injury through cutting. In addition, if the wavelength range of the radiation and the power density at the tissue-pressing surface are suitably chosen, it is possible to prevent excessive change in the surface of the tissue adjacent the tissue-pressing member, and coagulation can instead begin at a certain depth in the tissue.

Advantageously, the high, rapid heat-dissipating capacity are obtained by using a tissue-pressing member having a inherent high heat capacity and inherent heat-dissipating power. Alternatively, means can be provided for dissipating heat from the tissue-pressing surface, i.e. some sort of cooling member or cooling device as a "heat sink". Accordingly, in either case the tissue-pressing member advantageously acts as a rapid-acting "heat sink", i.e. it rapidly dissipates heat from the region of tissue adjacent the pressure surface, so that the adjacent tissue is not excessively heated. By the rounding of the edges of the tissue-pressing member injury through cutting, and excessive concentration of radiation at the edges which could cause increased adhesion of tissue, are avoided.

At 20°C the pressure-member material should have a temperature resistance of

$$R_T = \frac{c \rho}{\lambda} \leq 20 \text{ s cm}^{-2}$$

In this expression:

120 s = time in seconds

c = specific heat [$\text{J g}^{-1} \text{K}^{-1}$]

ρ = density [g cm^{-3}]

λ = thermal conductivity [$\text{J cm}^{-1} \text{s}^{-1} \text{K}^{-1}$]

125 Preferably $R_T \leq 10 \text{ s cm}^{-2}$. In the case of sapphire the temperature resistance is approx. 7 s cm^{-2} at 20°C .

In view of the initially-mentioned value of the average thickness d of the pressure member, the following value is preferred for the thermal capacity Γ per unit area of the pressure member (= thermal

capacity of the pressure member per unit pressure surface):

$$\Gamma = c \cdot \rho \cdot \bar{d} > 0.4 \text{ J cm}^{-2} \text{ K}^{-1}.$$

Of course, the tissue-pressing member is made of a material which is capable of transmitting, e.g. preferably transparent or at least translucent to, the incoherent radiation producing coagulation. If there is a risk of dazzling, the lower limit of the radiation range may advantageously be approx. 0.6 to 0.7 μm .

The following materials, in the following order of preference, are particularly suitable for the tissue-pressing member: sapphire single crystals, MgO , BeO , monocrystalline quartz, also if desired TiO_2 , SiTiO_3 , and ZrO_2 .

The invention may be carried into practice in various ways but certain specific embodiments thereof will now be described in detail with reference to the accompanying drawings. Other embodiments and advantages of the radiation coagulator according to the invention will also be discussed. In the drawings:

Fig. 1 is a side view, partly in axial section, of a first and preferred embodiment of the invention;

Fig. 2 is a view similar to Figure 1 of a variant of the embodiment of Fig. 1;

Fig. 3 is a plan view of the radiation outlet system of the coagulator in Fig. 2 as seen from the line III-III in Fig. 2;

Figs. 4 and 5 are axial sections through two other embodiments of the invention;

Fig. 4a shows graphically the relationship of the tissue temperature with radiation penetration depth produced by the coagulator of Fig. 4;

Figs. 6 and 7 are side views of other constructions of radiation outlet systems for radiation coagulators embodying the invention and

Fig. 7a is a graph similar to Figure 4a relating to the use of the coagulator of Fig. 7.

Fig. 1 shows partly in axial section a substantially cylindrical, rod-shaped radiation coagulator, which is the present preferred embodiment of the invention. It comprises a handle member in the form of a thick-walled tube 10, preferably of non-rusting steel. An ellipsoidal reflector 12 is formed by boring or the like in the front end of tube 10 and its surface is highly polished and preferably gilded. In front of the reflector 12 is an incandescent filament lamp 14 serving as a source of light and heat radiation, for example a tungsten-halogen low-voltage lamp, closely surrounded by the reflector 12. The radial spacing between the lamp bulb and the reflector is preferably not more than 5mm, preferably about 2mm. A connecting lead 16 extending along the central bore of tube 10 connects the lamp 14 to a flexible lead 18, which is preferably fitted in liquid-tight and vapour-tight manner in the rounded rear end of tube 10. At its far end the lead 18 is connected through a switch 32 and transformer 31 to an electric power source 30, for energising the lamp.

The tube 10 has a front part 10a having a somewhat smaller diameter, on which a thin-walled tube 20 made e.g. of non-rusting steel is placed, the tube 20 being dimensioned so that its outside is substantially flush with the outside of the rear part 10b of tube 10. A tissue-pressing member 22 comprising a cylindrical piece of a single sapphire crystal is

inserted in the front end of tube 20. The member 22 is adhered to the tube 20 by a layer 24 of silicone adhesive resistant to elevated temperatures. The cylindrical outer surface 22a of the member 22 is highly polished so that member 22 can act as a short light guide. The annular front edge 22b of the member 22 is rounded (the radius of curvature can be e.g. 0.5 mm) so that there is no risk of sensitive tissue being injured by the edge of the flat end face 22c which forms the pressure surface for application to the tissue.

The diameter of the member 22 may be 16 mm and its axial length 6 - 8 mm, up to 15 mm.

The layer 24 of silicone adhesive does not interfere with the transmission of light, since its index of refraction is below that of the sapphire.

The part 10a of the tube 10 has an annular groove receiving an O-ring seal 26. The O-ring seal, the layer 24 of silicone adhesive and the seal at the inlet of cable 18 at the rear end of the tube 10 ensure that the coagulator of Fig. 1 can be steam-treated in an autoclave without risk of vapour penetrating inside and possibly damaging the reflector 12 or other internal parts of the coagulator.

A dielectric thin-layer filter 28 can be vapour-deposited on the radiation inlet surface of the member 22 facing the lamp 14, so as to restrict the lower limit of the transmitted spectrum region to e.g. 600 μm , thus reducing the dazzling effect of the emergent radiation. Alternatively or additionally the sapphire forming the tissue-pressing member 22 can in known manner be doped with chromium ions so as to become red, thus likewise reducing the dazzling effect. Moreover, in the case of a radiation coagulator of the kind shown in Fig. 1, the portion of the member 22 projecting from tube 20 is kept very short, more particularly shorter than 10 mm, preferably shorter than 3 mm, more particularly about 1 mm.

If an incandescent lamp 14 having a rated power of 250 W is used, the front end of the reflector 12 and the cylindrical tissue-pressing member 22 preferably have a diameter of about 16 mm. If the member 22 has a diameter of 12 mm or 25 mm, the incandescent lamp used will advantageously have a rated power of 150 W or 400 W respectively. These values will ensure a radiation power density at the surface 22c which is sufficiently high but is less than 150 W/cm^2 .

The temperature distribution occurring during coagulation is similar to that described hereinafter with reference to Fig. 7.

Figures 2 and 3 show a coagulator differing in two ways from that in Fig. 1. Firstly, the tube 10' is bent at an angle α preferably between about 90° and 150°. Secondly, the tissue-pressing member 22' has a wedge-shaped tapering end, to facilitate coagulation in cracks in the tissue, e.g. if the liver is damaged in an accident. However, all the exposed edges of the wedge-shaped member 22' are rounded, so that they cannot cut or injure.

The tube 20' can be externally corrugated (not shown) to facilitate turning it, so as to alter the orientation of the entire front edge 22'd of the wedge relative to the tube 10'. In the present case therefore, the member 22' has two flat pressure surfaces 22'c. As

before, the cylindrical parts 22'a of the side surfaces are highly polished. The wedge angle of the member 22' can be e.g. between 40° and 90°, preferably about 60°. Of course it must not be so small that radiation is totally reflected and prevented from coming out, and it is chosen to be large enough, for a given value of the diameter of the cylindrical part 22'a, to ensure that the average thickness of solid material of the member 22', measured at right angles to either pressure surface 22'c and taken across its whole width from the edge 22'd, is not less than 4 mm. Assuming a 12 or 16 mm diameter for part 22'a and a wedge angle of 40°, this limit will be substantially exceeded.

In the coagulators in Figs. 1 and 2, the lamp 14 is preferably disposed at a short distance from the light inlet surface of the tissue-pressing member 22 or 22' but without touching it. The distance can be e.g. 1 to 2 mm.

The embodiment shown in Fig. 2 can be modified by replacing the bent tube 10' by a rod-like member containing a flexible part so that the angle α can be adjusted as required. The flexible part can be for example a corrugated tubular hose.

Another variant of the aforementioned embodiments consists in using a tissue-pressing member in the form of a cylindrical rod having one flat end face through which light enters and which extends at right angles to the axis, whereas the other flat end face, which presses the tissue, extends at an angle to the axis. As before, the angle between the oblique surface and the axis must not be so great that radiation is totally reflected and prevented from coming out. In this embodiment also, all exposed edges are rounded so that they cannot cause injury. Alternatively the pressing member can be in the form of an oblique cylinder, i.e. one having parallel radiation inlet and outlet surfaces extending obliquely to the central direction of radiation.

Finally, use may also be made of a tissue-pressing member in the form of a prism having two surfaces at an angle of 90° to one another, one surface being for incoming light radiation and the other being the pressure surface for application to the tissue. The prism also has an oblique surface at which the light entering through the light inlet surface is reflected towards the pressure surface through which it leaves the prism.

Fig. 4 shows a radiation reflector which in principle can be constructed in the manner described with reference to Fig. 1 of German OS 27 17 421. It contains a heat-radiation source in the form of a tungsten-halogen low-voltage filament lamp 114 and a reflector 112 in the form of a concave aluminium reflector. The aluminium reflector can be replaced by a reflector comprising a reflecting layer of gold or a dielectric thin-layer reflector which selectively reflects at wavelengths between about 0.6 and 1.4 μm .

The coagulator in Fig. 4 also includes a rigid light guide 121 in the form of a quartz rod having a circular cross-section and surrounded by a thin metal tube 120. The reflector 112 reflects heat radiation from lamp 114 into the entry end of the light guide 121. A tissue-pressing member 122 is disposed at the radiation exit end of the light guide 121 and is a

cylindrical rod of e.g. clear, monocrystalline sapphire having an optically polished side surface 122a and having the same diameter as and in line with the rod-shaped light guide 121. The front end of the member 122, remote from the light guide 121, forms a flat pressure surface 122c which is highly-polished and scratch-free. The front end of the member 122 is rounded at its edge so as not to cut the tissue 125.

In the known proposal of the aforesaid German O.L.S. specification the tissue-pressing member was to be a very thin plate, which served the purpose only of reducing the adhesion of the pressure surface. In the present case the tissue-pressing member also serves to prevent excessive heating of the surface of tissue 125 against which the tissue-pressing surface 122c is applied. To this end, in the coagulator according to Fig. 4, the cylindrical tissue-pressing member 122 has a relatively considerable length L and an adequate cross-section. The length L is greater than 4 mm, advantageously at least 6 mm, more particularly 10 mm or more. The tissue-pressing member 122 can have a diameter between 4 and 10 mm. In order to obliterate blood vessels in deep-lying tissue, using a lamp 114 having a rated power of e.g. 150 W and a light-guide 121 whose length is about 10 to 20 cm, the diameter should advantageously be about 6 mm.

As a result of its dimensions, in particular its axial length the cylindrical tissue-pressing member 122 has sufficient heat capacity to ensure that during a normal treatment cycle of about 2 seconds, it is not heated so strongly as to produce undesirable changes in the tissue surface. During a treatment period of 2 seconds, the temperature rise at the pressure surface 122c should advantageously be not more than 50°C, advantageously not more than 30°C or preferably not more than 20°C, if the coagulator is used for obliterating deep-seated blood vessels.

When the radiation is at wavelengths from 0.6 to 1.4 μm which are mainly absorbed only inside the tissue, the temperature curve T in dependence on the depth of penetration d is as shown by the curve 127 in Fig. 4a. During irradiation for about 15 seconds the temperature at a region 129 inside the tissue 125 increases sufficiently for coagulation and obliteration to occur there, i.e. the temperature rises to about 80° or 90°C. In a region adjacent the pressure surface 122c down to a depth of d₁, the cooling effect of the pressure member 122 pressed against the tissue 125 is sufficient to prevent the temperature required for coagulation from being reached. Likewise at a depth d₂ onwards, the radiation is too weak to reach the coagulation temperature.

Fig. 5 shows a radiation coagulator which, like that in Fig. 4, comprises a tungsten-halogen incandescent lamp 214, a reflector 212, a light-guide rod 221 and a cylindrical tissue-pressing member 222 with its flat pressure surface 222c. An optical filter 125 is disposed between the lamp 214 and the light-inlet end of the rod 221 and is in the form of a cell containing an aqueous solution of a red dye. A dielectric thin layer filter having a corresponding pass band is an advantageous alternative. The filter 215 absorbs short-wave radiation including UV radiation and the long-wave infrared, so that the radiation entering the

light-guide rod is substantially restricted to wavelengths between 0.6 and 1.4 μm . The pressure member 222 is disposed close to the light outlet end of rod 221 and is surrounded by a cooling device 230, which can be a cooling member having ribs, of the kind used for transistors, or can be a cell filled with liquid and also having cooling ribs 230a if required. As before the axial length of the cylindrical tissue-pressing member 222 exceeds 4 mm.

- Fig. 6 shows an alternative to the cooling device 230 in Fig. 5. Fig. 6 shows a tissue-pressing member 322 comprising a relatively large disc, not less than 4 mm in axial thickness with a pressure surface 322c. Radiation S travels only through its central part 322'. Accordingly, coagulation occurs only at the central part. The outer part, which surrounds the central part 322' serves as a cooling member or heat sink. Radiation can be restricted to the central part 322' by a frusto-conical light-guide 321 having a polished surface 321a. The tissue-pressing members 222 and 322 are preferably made of a material having high thermal conductivity, e.g. beryllium oxide. Suitable beryllium oxide members can be cheaply produced e.g. by hot pressing and sintering, and are sufficiently transparent for the present application.

- Fig. 7 shows a light outlet system comprising a light-guide rod 422 which also serves as a tissue-pressing member. It has a frusto-conical end 422d, forming a tissue-pressing surface 422c. The light-guide 422 is made of a crystalline, transparent material of the aforementioned kind having high thermal conductivity, so that the member 422 dissipates heat from tissue 429 adjacent the pressure surface 422c, which serves as a light outlet surface. If unfiltered radiation is used from a 150 W tungsten-halogen lamp operated at a colour temperature of about 3 000 K, and the rod 422 has a length of 50 mm or at least 10 mm and is made from a sapphire single crystal having a tissue-pressing surface 422c about 2 to 6 mm in diameter, the resulting coagulation region 429a can extend deeply into the tissue 429. The resulting temperature distribution, in dependence on the distance d from the outer surface of the tissue (i.e. the skin) corresponds to the continuous curve in the graph in Fig. 7a. Because of the heat dissipated by the rod 422, which acts as a cooling member, the temperature at the tissue surface is limited to a moderate value T_2 , which is above the coagulation temperature T_3 , but not high enough to cause carbonization or excessive adhesion of the tissue to the light outlet surface 422c. To some extent, the heat dissipation compensates for the drop in the intensity of the radiation penetrating the tissue, so that the temperature curve down to a considerable depth is relatively flat and the temperature is above the coagulation temperature T_3 . If the tissue-pressing member is made of a poor conductor of heat, such as quartz glass or plastics, the resulting temperature distribution corresponds to the broken curve, where the tissue surface reaches a very high temperature T_1 after a short time. As a result, the tissue becomes carbonized at the surface which prevents deep penetration of radiation, so that bleeding is stopped less efficiently and the tissue tends to stick to the pressing surface. Similar effects occur if the sapphire

or other pressure member is too thin.

- In each of the embodiments of the invention described above, the electric input power of the radiation source, i.e. the incandescent electric lamp, should usually be at least 75 W, preferably at least 100 W. To obtain efficient coagulation, the power density should usually be at least 10 W/cm² or more in the radiation-transmitting cross-section of the tissue-pressing member at the pressure surface. The power density should preferably be not more than 100 W/cm², to prevent excessively fast heating of the tissue at the pressure surface, with the consequent risk that the tissue at the pressure surface will dry too quickly and become undesirably adhesive. In no case does the power density exceed 150 W/cm².

- Moreover as explained in each of the specific embodiments described and illustrated the thickness of solid material of the tissue-pressing member, measured at right angles to the or each pressure surface and averaged over the entire width of the pressure surface, is not less than the preferred minimum value of 4 mm. In the variation referred to where the tissue-pressing member is a right-angled prism one of whose short sides is the radiation inlet surface and the other of which is the pressure surface, the thickness value varies linearly over the whole width of the pressure surface from zero or near-zero at the leading edge of the pressure member to the full length of the other short side, so that the average value is roughly half the length of the latter short side. If that side is say 12 mm long the average thickness value will be 6 mm, and in any case it should preferably not be less than 4 mm.

- In the possible case referred to of tissue-pressing members of oblique cylindrical form or of cylindrical form with only the pressure surface oblique to the cylinder axis, the thickness of material will have to be averaged over the width of the pressure surface and should preferably not be less than 4 mm.

105 CLAIMS

1. A radiation coagulator comprising a source of heat radiation in the form of an electric incandescent filament, an electricity supply circuit for the incandescent filament and a radiation outlet system including a radiation-transmitting tissue-pressing member made of a crystalline dielectric material through which the heat radiation passes, the tissue-pressing member having a pressure surface for application to body tissue, and characterised in that the radiation power density at the pressure surface is not more than 150 W/cm², and the thickness of the tissue-pressing member measured at right angles to and averaged over the pressure surface, is at least 4 mm.
2. A radiation coagulator comprising a source of heat radiation in the form of an electric incandescent filament, and a radiation outlet including a radiation-transmitting tissue-pressing member made of a crystalline dielectric material capable of transmitting the heat radiation and affording a pressure surface for application to body tissue to be treated, and characterised in that by virtue of the shape and dimensions of the tissue-pressing member and the thermal conductivity and thermal capacity of its material, in conjunction with an associated heat sink

if required, the member in use exerts a substantial and rapid heat-removal and cooling effect on the tissue immediately adjacent to its pressure surface.

3. A radiation coagulator according to Claim 1 or
5 Claim 2 characterised in that the radiation power density at the pressure surface is not more than 100 W/cm².

4. A radiation coagulator according to Claim 1 or Claim 2 or Claim 3, characterised in that the power
10 density of the incoherent radiation at the pressure surface is at least 10 W per square centimetre.

5. A radiation coagulator according to any one of Claims 1 to 4, characterised in that the radiation outlet system has a heat-dissipating capacity such that
15 whilst the pressure surface is applied to the body tissue and the heat radiation from the source is passing through it, the temperature at the pressure surfaces rises by not more than 50°C in two seconds.

6. A radiation coagulator according to any one of
20 the preceding claims, characterised in that the tissue-pressing member does not have any exposed sharp, cutting edges capable of coming in contact with body tissue.

7. A radiation coagulator according to any one of
25 the preceding claims, characterised in that the tissue-pressing member, adjacent at least one radiation inlet surface, has a circular cross-section having a diameter of at least 4 mm and is at least 6 mm long in the direction of radiation.

8. A radiation coagulator according to any one of
30 Claims 1 to 6, characterised in that the side of a radiation-transmitting part of the tissue-pressing member is connected in an efficiently heat-conductive manner to a heat sink.

9. A radiation coagulator according to any one of
35 Claims 1 to 7, characterised in that the source of heat radiation is an electric incandescent lamp having a rated power of 150 W, 250 W or 400 W, and that the tissue-pressing member is cylindrical at least adjacent a radiation inlet surface thereof, has a length of
40 at least 5 mm in the direction of radiation, and has a diameter of 12 mm, 16 mm or 25 mm respectively for the previously-mentioned rated lamp powers.

10. A radiation coagulator according to Claim 9
45 characterised in that the light inlet surface of the tissue-pressing member is not more than 10 mm from the incandescent lamp bulb and there is no light-guide between the incandescent lamp bulb and the light inlet surface of the tissue-pressing member.

11. A radiation coagulator according to any one
50 of the preceding claims, characterised in that the tissue-pressing member is at least 10 mm long.

12. A radiation coagulator according to any one
55 of the preceding claims, characterised in that the tissue-pressing member has a tapering end remote from the source of radiation.

13. A radiation coagulator according to Claim 12,
characterised in that the tapering end is wedge-shaped.

14. A radiation coagulator according to any one
60 of the preceding claims, characterised in that the tissue-pressing member is made essentially of aluminium oxide, beryllium oxide or magnesium oxide.

- 65 15. A radiation coagulator according to Claim 14,

characterised in that the tissue-pressing member is made from a sapphire single crystal.

16. A radiation coagulator according to any one
70 of the preceding claims, characterised in that the tissue-pressing member contains a material giving increased absorption in the green and blue spectrum range.

17. A radiation coagulator according to any one
75 of the preceding claims, characterised in that an optical filter having a pass band from 0.6 μ m is disposed between the source of radiation and the tissue-pressing member.

18. A radiation coagulator according to any one
80 of the preceding claims, characterised in that the radiation source is an incandescent lamp in combination with a substantially ellipsoidal reflector having a radial distance of not more than 5 mm from the lamp bulb.

19. A radiation coagulator according to any one
85 of the preceding claims, characterised in that the source of radiation is an incandescent lamp having a rated electric power of at least 100 W.

20. A radiation coagulator according to any one
90 of the preceding claims, characterised by an optical element disposed in the path of the rays between the radiation source and the tissue-pressing surface and limiting the radiation substantially to a wavelength range of 0.6 to 1.4 μ m.

21. A radiation coagulator substantially as speci-
95 fically described herein with reference to Figure 1, or to Figures 2 and 3, or to Figure 4, or to Figure 5, or to any one of those constructions when modified in accordance with Figure 6 or Figure 7 of the accompanying drawings.

Printed for Her Majesty's Stationery Office by The Tweeddale Press Ltd.,
Berwick-upon-Tweed, 1981.
Published at the Patent Office, 25 Southampton Buildings, London, WC2A 1AY,
from which copies may be obtained.

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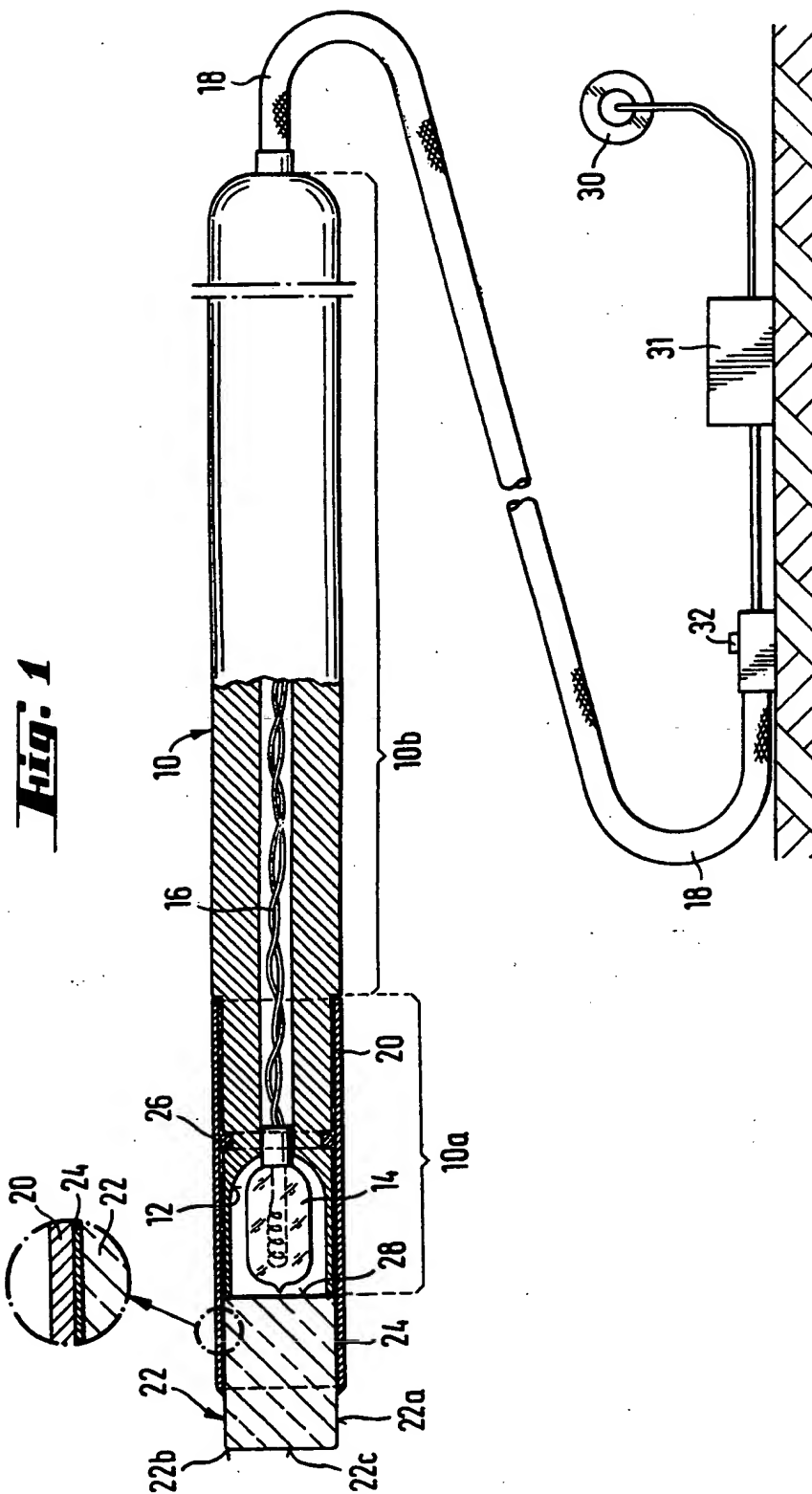
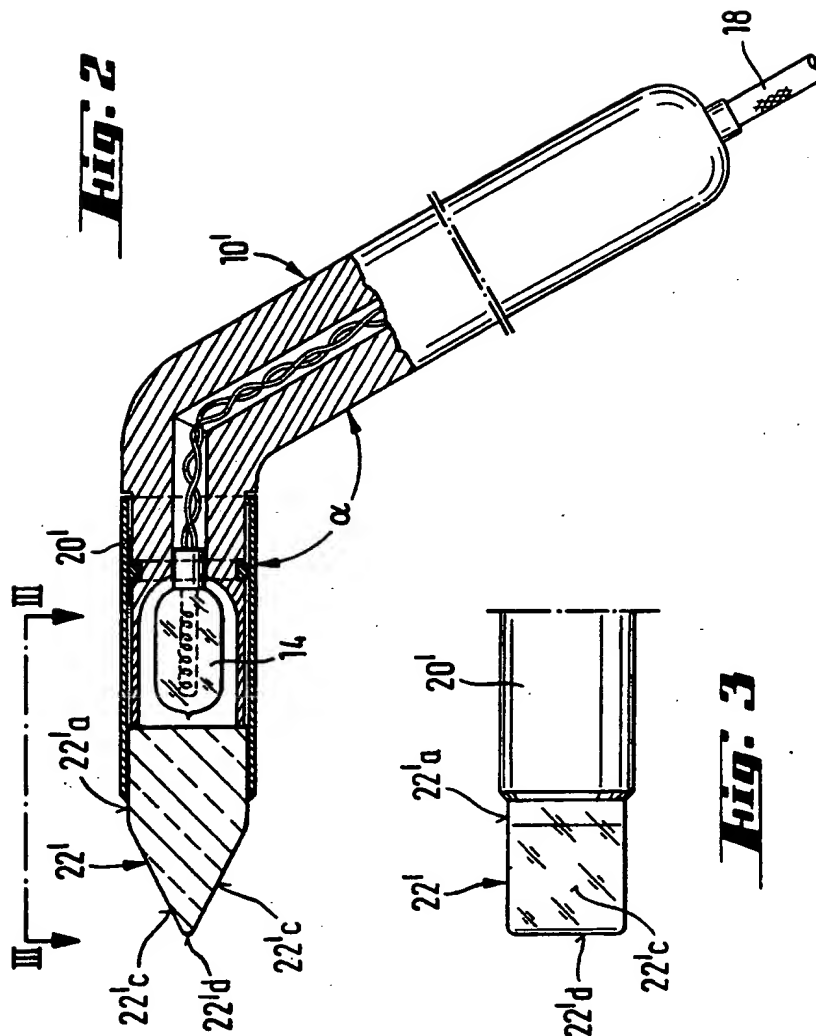
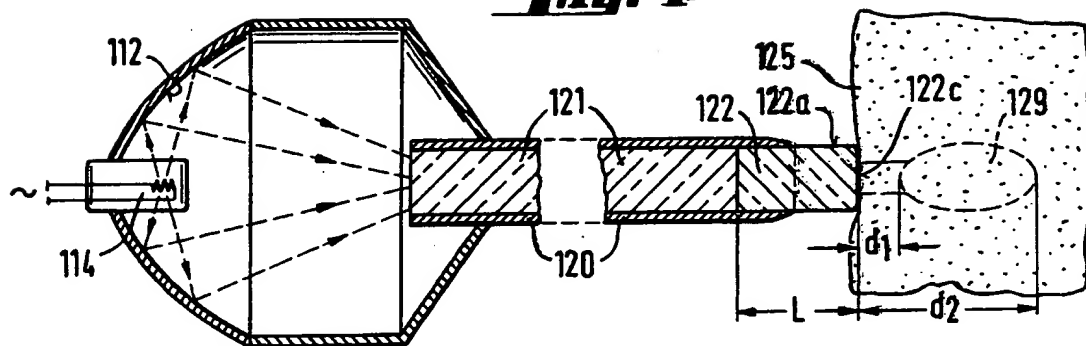
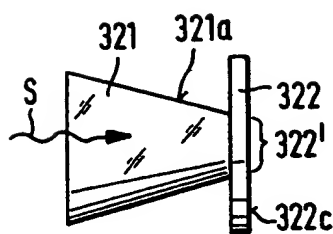
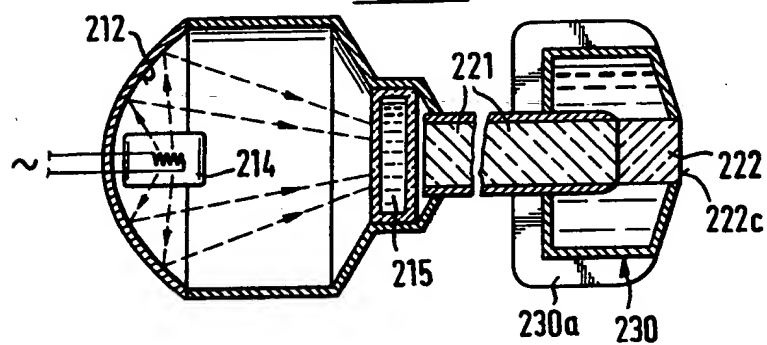
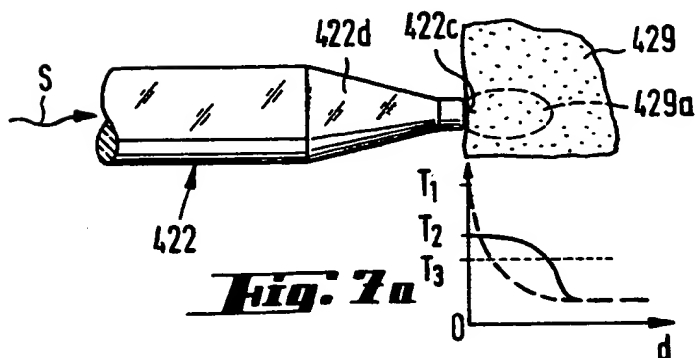


Fig. 1

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Fig. 4**Fig. 4a****Fig. 5****Fig. 6****Fig. 7****Fig. 7a**